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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,979	10/24/2003	William R. Campbell	PIED1110-1	1729
7590 STACY L. TAYLOR DLA PIPER US LLP Suite 1100 4365 Executive Drive San Diego, CA 92121-2133				
			EXAMINER	
			LEVY, NEIL S	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			12/02/2010 PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/692,979

Applicant(s)

CAMPBELL ET AL.

Examiner

NEIL LEVY

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 12-16 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12-16 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 12-15 stand rejected under 35 U.S.C. 103(a) as obvious over SINGER et al 4147800

IPM (Table 1) at about 70%, with polysorbate and water carrier, killed 100% lice (column 4, lines 21-32). Table I shows 82- 100% killed with 70 -78% IPM. Examples are with human lice, obviously inclusive of all species. Curve 2 is only IPM (COL. 4, LINE 23-26) & POLYSORBATE @ 70%, WITH DEATH IN A 2 MINUTE TEST thus meeting the instant claims. NO OTHER AGENTS are needed, only IPM. As to the retention, examples show shampoos, lotions. Only shampoos would have a short time of retention, but lotions would be applied as is known in the art, without intentional removal; thus, retention of hours.

Claim 1-4, 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over SINGER

See above; Table I shows IPM alone kills 100% of lice, obvious to use prevent alcohol irritation (column 3, top) if subject is sensitive.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize pest control means, to use any of art recognized means, as of the ectoparasitocidal, pediculicide compositions to control lice, modified as desired to decrease toxicity to patients.

All the critical elements of the instant are disclosed. The amounts and proportions of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of the composition to optimize the effect desired, to optimize reduction of toxicity, cost minimization, enhanced, and prolonged, or synergistic effects.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability. Applicant's concentrations at the high end are lethal; at the low end are neither shown in the specification to be effective, nor are they shown by SINGER to be effective @ the 82 % mortality level now claimed.

Claims 12-16, 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over SINGER et al 4147800 in view of REID et al 5972987 and further in view of Von Bittera et al 4544547.

SINGER (above) kills lice, but does not mention combing.

REID shows application of pediculicide and dye (column 4, lines 6-11) permit removal with combs (column 4, lines 50-56) from human or animal (lines 63-66) particularly head lice (column 5, lines 44-48). Example 1 shows use of silicone and IPM.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize pest control means, to use any of art recognized means, as of the pediculicide compositions of SINGER to control lice, modified as desired to decrease toxicity to patients. Motivation to combine springs from the IPM synergy of SINGER, with further removal of lice and nits facilitated by dye and comb of REID.

Von Bittera shows the application of IPM (example 2) in the control of ectoparasites of dogs & cats, including dog flea, dog louse, & ticks (col. 12, lines 23-40).

All the critical elements of the instant are disclosed. The amounts and proportions of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of the composition to optimize the effect desired, to optimize reduction of toxicity, cost minimization, enhanced, and prolonged, or synergistic effects.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the administration of the particular ingredients' or the manner of treating lice, combing, shampooing, rinsing, or ingredient concentrations provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability

Response to Arguments

Applicant's arguments filed 9/17/10 have been fully considered but they are not persuasive. Applicant argues that only IPM kills now; but in fact SINGER shows only IPM kills. IT'S NOT the preferred or synergistic formulation, but it meets the instant claims. The argument as to only toxic levels of 50 + % kill is not sustainable, as applicant requires only 10 % & SINGER shows this concentration less effective e than the 82 % instantly claimed lethality. There is no explanation of how IPM in SINGER differs from that of the instant, nor is there anything different in the instant methods and those of SINGER. A reading of the secondary references, all directed at ectoparasite control, with SINGER, is not seen as teaching away from the application of IPM in the control of ectoparasites, As SINGER shows no more is needed than IPM.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT A. WAX can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NEIL LEVY/
Primary Examiner, Art Unit 1615 11/26/2010